4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard (Broad Institute) for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. FDA revoked this Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay is revoked as of May 5, 2022.

ADDRESSES: Submit a written request for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocation may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On July 8, 2020, FDA issued an EUA to the Broad Institute for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorization were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Request

In a request received by FDA on April 4, 2022, Broad Institute requested revocation of, and on May 5, 2022, FDA revoked, the Authorization for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. Because the Broad Institute notified FDA that it has decided to discontinue use of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay and requested FDA revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, FDA has

determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocation is available on the internet at https://www.regulations.gov/.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Broad Institute for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

May 5, 2022

Chuck Kolifrath
Associate Director, Regulatory Affairs, Genomics Platform
Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141
Re: Revocation of EUA200147

Dear Mr. Kolifrath:

This letter is in response to the request from Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard ("Broad Institute of MIT and Harvard") received on April 4, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay issued on July 8, 2020, re-issued on October 23, 2020, December 18, 2020, and June 10, 2021, and amended on August 30, 2020, and September 23, 2021. The Broad Institute of MIT and Harvard indicated that it is no longer conducting testing under this EUA.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because the Broad Institute of MIT and Harvard has notified FDA that it has decided to discontinue use of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay and requested FDA revoke the EUA for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200147 for the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Niall J. Lennon, Ph.D., Institute Scientist and Sr. Director, Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard

Dated: May 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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